

## **REMARKS**

### **A. BACKGROUND**

The present Amendment is in response to the Office Action mailed July 8, 2009. Claims 3-7 and 27-35 were pending and rejected in view of cited art.<sup>1</sup> Claims 3, 5, 29, and 31-32 are amended and claim 27 has been canceled. Claims 3-7 and 28-35 are now pending in view of the above amendments.<sup>2</sup>

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

### **B. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Paragraphs 3-5 of the Office Action rejected claims 5-7 and 31-33 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 5, claims 3 and 5 have been amended, with claim reciting, in part, "the distal edge of the opening in the side of the cutting member is a sharpened edge." Dependent claim 31 has been amended to recite, in part, "the opening has a proximal edge, the cutting member being adapted to engage the proximal edge to sever suture when suture is disposed through the groove and opening."

Applicant respectfully submits that by these amendments claims 5-7 and 31-33 are now in compliance with 35 U.S.C. § 112, second paragraph and respectfully requests that the rejection be withdrawn.

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<sup>1</sup> Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

**C. PRIOR ART REJECTIONS**

**I. REJECTION UNDER 35 U.S.C. §102(B)**

Paragraphs 6-7 of the Office Action rejected claims 3-4, 27-30, and 34-35 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,059,201 (*Asnis*). Applicant respectfully disagrees.

*Asnis* was cited as disclosing "a shaft 24 having a proximal end and a distal end and an axis therebetween, the shaft having a groove (lumen) formed in a side thereof, the groove extending from the distal end toward the proximal end and being in communication with an opening formed in the side (proximal tip) of the shaft" (Office Action, page 3). Accordingly, the outer tube 24 of *Asnis* was identified as the shaft of claim 3 and the opening in the end of the outer tube 24 as the opening in the side of the shaft of claim 3. Further, *Asnis* was cited as teaching "a cutting member 102 (cutting surfaces 106, 108 which face proximally, Figures 3-4) slidably disposed within the shaft, a suture retainer 202 slidably disposed within the shaft and within the cutting member, the suture retainer having a suture protector 206 in an exterior surface of the suture retainer" (Office Action, page 3). Accordingly, the Office Action identified the inner tube 102 as the cutting member of claim 3 and the extractor shaft 202 as the suture retainer of claim 3.

*Asnis* teaches a suture threading, stitching, and wrapping device. (Title). "[I]nner tube assembly 100 comprises tube 102 and pivot assembly 104. Tube 102 is sized to slide freely inside outer tube 24" (Col. 5, ll. 8-10). "[E]xtractor assembly 200 comprises a shaft 202 that is sized to slide freely inside inner tube 102" (Col. 5, ll. 40-42). "[E]xtractor assembly 200 is urged forward within inner tube 102 toward the clamped tissue piece 404 until curved contact surface 214 of extractor assembly 200 engages curved contact surface 320 of upper portion 308" (Col. 9, ll. 16-19). "As extractor assembly 200 is pressed forward, its pointed end 204 will pass through bore 34 in bracket rear wall 32, through tissue piece 404, and through bore 36 in bracket front wall 28" (Col. 9, ll. 21-25). "Extractor assembly 200 is then caused to move rearwardly in the inner tube 102 by pulling rearwardly on extractor knob 208. As extractor shaft 202 is moved rearwardly, the slot 206 in the shaft 202 passes beneath suture segment 402 and the latter either drops into slot 206 or is caught and forced into slot 206" (Col. 9, ll. 39-45). "As the extractor assembly 200 is pulled rearwardly, its pointed end 204 passes back through tissue piece 404 and

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<sup>2</sup> Support for the claim amendments and/or new claim(s) can be found throughout the specification and/or drawings as originally filed.

into inner tube 102. Because suture segment 402 is captured in slot 206, as extractor shaft 202 is moved rearwardly, segment 402 is drawn through the tissue piece 404 and into inner tube 102" (Col. 9, ll. 49-54). "Upon completion of the foregoing procedure, the extractor assembly 202 is urged forward so that the slot 206 projects out of the front end of the outer tube 102. Mid-length section 402 of suture 400 is then removed from the slot and is anchored outside the surgical site" (Col. 10, ll. 17-21).

In direct contrast, claim 3 recites, in part, "a shaft having a proximal end and a distal end and an axis therebetween, the shaft having a groove formed in a side thereof, the groove extending from the distal end toward the proximal end and being in communication with an opening formed *in the side of the shaft*, the opening disposed *proximal the distal end* of the shaft and including a *proximal edge*; a cutting member slidably disposed within the shaft; and a suture retainer slidably disposed within the shaft and within the cutting member" (*emphasis added*). Claim 3 also recites, "the cutting member having a distal end and a proximal end, the distal end having a lumen defined therein and opening in the side of the cutting member in communication with the lumen and disposed proximal the distal end of the cutting member, *wherein the opening in the side of the cutting member forms a distal edge*" (*emphasis added*). Claim 3 further recites, "the second lever [being] operatively coupled to the cutting member to move the cutting member within the shaft and around the suture retainer to move *the distal edge of the cutting member into proximity with the proximal edge of the opening formed in the side of the shaft to cut the suture*" (*emphasis added*).

Such a configuration is not taught or suggested by the device of *Asnis* in which "suture segment 402 is captured in slot 206, as extractor shaft 202 is moved rearwardly, segment 402 is drawn through the tissue piece 404 and into inner tube 102" as taught by col. 9, ll. 49-54, after which "the extractor assembly 202 is urged forward so that the slot 206 projects out of the front end of the outer tube 102. Mid-length section 402 of suture 400 is then removed from the slot and is *anchored outside* the surgical site" as taught at col. 10, ll. 17-21 (*emphasis added*).

Independent claim 29 recites, in part, "a shaft having a proximal end and a distal end and an axis therebetween, a bore extends from the distal end toward the proximal end and communicates with a groove formed in and through a wall of the shaft, the groove extends from the distal end toward the proximal end and is in communication with the bore and an opening formed in the side of the shaft, . . . a fitting received within the bore of the distal end of the shaft, the fitting having a fixture fitting end, a fitting proximal end, and a fitting groove extending from

the fitting distal end toward the fitting proximal end, the fitting groove and the groove being aligned when the fitting is received within the bore."

The Office Action does not identify, and Applicant has been unable to identify "a fitting received within the bore of the distal end of the shaft, . . . the fitting groove and the groove being aligned when the fitting is received within the bore," as recited, in part, by independent claim 29. The clamping bracket 26 of *Asnis* "is attached to the distal end of outer tube 24 via its rear wall 32", however no mention is made of this clamping bracket 26 being "received within the bore of the distal end of the shaft."

Since *Asnis* does not teach the device recited in claims 3 and 29, Applicant respectfully requests that the rejection under 35 U.S.C. § 102(b) be withdrawn. Claims 4 and 28 and claims 30 and 34-35 depend from claims 3 and 29, respectively, and are allowable for at least the same reasons as claims 3 and 29.

## **II. REJECTION UNDER 35 U.S.C. § 103**

The Office Action rejected claims 5-7 and 31-33 under 35 U.S.C. § 103(a) as being unpatentable over *Asnis* in view of U.S. Patent No. 5,242,459 (*Buelna*). Applicant respectfully disagrees.

In particular, the Office Action indicates that *Asnis* "does not expressly disclose the shaft having an opening with a proximal edge, the sharpened edge of the cutting member being adapted to engage the proximal edge to sever the suture when suture is disposed through the groove and opening" (Office Action, page 4). The Office Action relies on *Buelna* to remedy these deficiencies and indicates that, "*Buelna* teach[es] an opening 38 of a shaft having a proximal edge and a cutting member 30 having a sharpened edge 36 which is adapted to engage the proximal edge to sever suture when suture is disposed through the groove and opening (Figures 4-6)" (Id.) Accordingly, the Office Action identified side aperture 38 as the opening of claims 5 and 31, the cutting member 30 as the cutting member, and the cutting edge 36 as the sharpened edge being adapted to engage the proximal edge of claims 5 and 31. However, *Buelna* makes clear that "[t]he plunger 62 thus causes the cutting member to axially advance in the distal direction, moving the cutting edge forward past the side aperture 38 . . . The cutting edge moving past aperture 38 causes a shearing action which can sever the free end 56 of the suture . . ." (*Buelna*, Col. 5, lines 49-52). As shown in FIGS. 4-6, the cutting edge 36 of *Buelna* extends

distally from the cutting member 30 such that causing the cutting member to axially advance in the distal direction causes the cutting edge 36 to engage a *distal edge* of the side aperture 38.

In direct contrast, independent claim 3, and by dependence claims 5-7, recite a device in which "the cutting member having a distal end and a proximal end, the distal end having a lumen defined therein and opening *in the side of the cutting member in communication with the lumen* and disposed proximal the distal end of the cutting member, wherein *the opening in the side of the cutting member includes a distal edge.*" In view of *Buelna's* failure to teach "*the opening in the side of the cutting member includes a distal edge*" and "the second lever [being] operatively coupled to the cutting member to move the cutting member within the shaft and around the suture retainer to move *the distal edge of the cutting member into proximity with the proximal edge of the opening formed in the side of the shaft to cut the suture,*" Applicant submits that the rejection is moot and respectfully requests that the rejection under Section 103 be withdrawn.

With respect to independent claim 29, *Buelna* fails to overcome the deficiency of *Asnis* with respect to "a fitting received within the bore of the distal end of the shaft, . . . the fitting groove and the groove being aligned when the fitting is received within the bore." The Office Action does not identify, and Applicant has been unable to identify such a fitting in the teaching of either *Asnis* or *Buelna*.

In view of the above, Applicant respectfully submits that *Asnis* and *Buelna*, whether alone or in combination, neither teach nor suggest the inventions claimed in independent claims 3 and 29. In addition, Applicant respectfully submits that for at least the same reasons *Asnis* and *Buelna*, whether alone or in combination, neither teach nor suggest the inventions claimed in dependent claims 5-7 and 31-33. Accordingly, Applicant respectfully requests that the rejection under Section 103 be withdrawn

#### **D. CONCLUSION**

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any

Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 9th day of November, 2009.

Respectfully submitted,

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